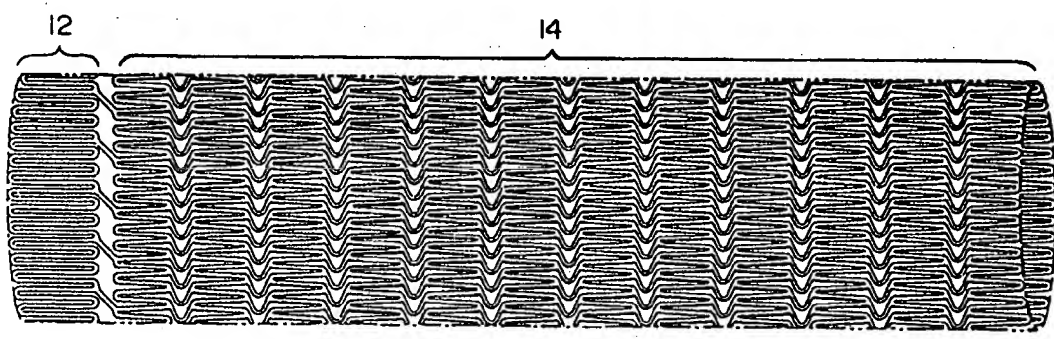


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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/06	A1	(11) International Publication Number: WO 99/60953 (43) International Publication Date: 2 December 1999 (02.12.99)
(21) International Application Number: PCT/US99/11602 (22) International Filing Date: 26 May 1999 (26.05.99) (30) Priority Data: 09/087,526 29 May 1998 (29.05.98) US (71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311 (US). (72) Inventor: VRBA, Anthony, C.; 12266 88th Place North, Maple Grove, MN 55369 (US). (74) Agents: ARRETT, Oliver, F. et al.; Vidas, Arrett & Steinkraus, P.A., Suite 2000, 6109 Blue Circle Drive, Minnetonka, MN 55343 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: BALLOON EXPANDABLE STENT WITH A SELF-EXPANDING PORTION		
		
(57) Abstract A stent consisting of at least two parts in juxtaposition, one part being of self-expandable characteristics while the other part is balloon expandable.		

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BALLOON EXPANDABLE STENT WITH A SELF-EXPANDING PORTION

Field of the Invention

The present invention relates to a new type of stent for transluminal
5 implantation and in particular new vascular stents.

Background of the Invention

Stents for transluminal implantation are well known. They are generally comprised of metallic supports which are inserted into a part of the human
10 body such as bile ducts, the urinary system, the digestive tube and notably by percutaneous route inside the blood vessels, usually the arteries in which case they are typically termed vascular stents. Stents are usually generally cylindrical and are constructed and arranged to expand radially once in position within the body. They are usually inserted while they have a first relatively small diameter and implanted in
15 a desired area, for example inside a vessel, then the stent is expanded *in situ* until it reaches a second diameter larger than the first diameter. A balloon associated with the catheter is usually used to provide the necessary interior radial force to the stent to cause it to expand radially. Self-expanding stents are also known which can expand from a first diameter to a larger second diameter without the use of a means for
20 applying an interior radial force, such as a balloon, to them. One such type of self-expanding stent is a stent made of a shape memory metal which expands to its second larger diameter upon exposure to body temperature. Such stents are also known.

Summary of the Invention

25 The present invention proposes a novel type of stent which combines a self-expanding part or portion with a part or portion which requires an interior radial force for expansion. More specifically, a stent for transluminal implantation according to the present invention will comprise cylindrical parts preferably in juxtaposition, with at least one part being self-expanding whereas another part
30 requires an interior radial force for its expansion, such as a balloon catheter or the like. Basically, the stent will consist of at least two of the aforementioned parts but may consist of more than two parts. Such an arrangement enables improved

placement of the stent by providing immediate expansion in part upon release of the stent from its delivery catheter.

Brief Description of the Figures

5 Figure 1 is a showing of one embodiment of a stent according to this invention;

 Figure 2 is a schematic showing of a stent similar to that of Figure 1 on a delivery catheter;

 Figure 3 is a schematic showing of the delivery system of Figure 2 with
10 the stent released for implantation;

 Figures 4 and 5 are schematic showings of a stent of the invention used in a vessel branching situation; and

 Figure 6 is a showing of another embodiment of a stent according to the invention, and

15 Figures 7-10 are schematic showings of bifurcated stents making use of the invention.

Detailed Description of the Preferred Embodiments

 Figure 1 shows a stent which combines self-expanding characteristics
20 and balloon expandable characteristics, i.e., requires expansion by use of a radial interior force. Preferably, the stent will have the self-expanding part 12 joined at one end in juxtaposition to the proximal end of a balloon expandable stent 14. The parts of the stent may be formed in accordance with any of the known stents extant in the prior art. Preferably however, the self-expanding part 12 will be of a shape memory
25 metal such as nitinol so as to enable self-expansion at body temperature upon release of the stent from its delivery catheter (not shown). The immediate expansion of part 12 aids in placement of the stent during release, following which a balloon or the like may be used to expand part 14.

 Part 12 may be of a larger diameter, or it may be flared to provide the
30 earliest possible contact with the body portion into which it is inserted, such as a vessel. This is best seen for example in Figures 2 and 3 which show a stent 10 similar to that of Figure 1 on a delivery catheter. Figure 2 shows the stent having the two

parts 12 and 14, respectively. Part 12 is the self-expanding part while part 14 requires a separate force for expansion such as a balloon 16 of a delivery catheter generally indicated at 18 inside the stent. In Figure 2, the stent is shown prior to release or deployment, the self-expanding part is enclosed by a retractable sheath 20.

- 5 In Figure 3, the sheath has been retracted, allowing self-expanding part 12 to flare outwardly. Subsequently, balloon 16 may be used in the known manner to expand part 14.

Since most stent delivery catheters include a retractable sheath which exposes the stent for implantation and removal from the catheter, if the self-expanding
10 part 12 is placed on the proximal end of the stent as shown, it will most likely be able to lock the stent in place until the remainder of the stent is expanded as by balloon expansion. This placement is preferable although placement in other parts of the stent proper may also be used.

When the self-expanding portion is placed at the proximal end of the
15 stent, such a stent is particularly useful in vessel stenting in which the vessel is of the bifurcating or branching type. Such a stent is shown schematically in figures 4 and 5 at 10. Figure 4 shows the stent having a proximal end part 12 which is self-expanding while the remainder of the stent body 14 is balloon expandable by balloon 16 on catheter 18. In Figure 4, the retractable sheath has been removed allowing the self-
20 expanding part to expand at the ostium 22 in a vessel 24 branching off of a main vessel such as aorta 26, helping to more accurately place the stent. Figure 5 shows the stent after expansion of part 14 by the balloon catheter and catheter retraction. A stent according to the present invention allows positive placement of the stent near the ostium of the bifurcation.

25 Stents according to the invention may also be comprised of more than one self-expanding and one balloon expandable part. Any combination of these parts is deemed to be within the scope of this invention. For example, referring to Figure 6, a stent 10 is shown having a self-expanding part 12 at each end of a balloon expandable part 14.

30 Referring now to Figures 7-10, bifurcated stents making use of the invention are described. Generally, bifurcated stents consist of three segments or components, a main trunk and two branches. In making use of this invention, any of

the three components may be made to be balloon expandable or self-expandable, as desired. For example, Figure 7 shows an unexpanded bifurcated stent 10 of one configuration in schematic form having a trunk 30, a first branch 32 and a second branch 34. As shown, trunk 30 is self-expanding, such as part 12 in the earlier
5 Figures, and branches 32 and 34 are balloon expandable, such as part 14 in the earlier Figures.

Figure 8 shows the stent of Figure 7 in an implanted position in a branching vessel 36.

Figure 9 shows another example of an unexpanded bifurcated stent 10
10 of another configuration in schematic form consisting of trunk 30 and branches 32 and 34. In this case, trunk 30 and branch 23 are both self-expanding and branch 34 is balloon expandable.

Figure 10 shows the stent of Figure 9 expanded in an implanted position in a branching vessel 36.

15 Trunk 30 in another embodiment may be balloon expandable while the branches 32 and 34 may be self-expandable.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations
20 are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

What is claimed is as follows:

1. A stent for transluminal implantation comprised of a cylindrical structure including at least two joined cylindrical parts one part being capable of radially self-expanding, the other part being radially expandable only by means of an interior radial force.
2. The stent of claim 1 wherein the two parts are in juxtaposition.
3. The stent of claim 1 wherein the other part is balloon expandable.
4. The stent of claim 1 wherein the one part is comprised of nitinol.
5. The stent of claim 1 wherein the one part comprises a proximal portion of the stent.
6. The stent of claim 5 wherein the one part is flared with respect to the rest of the stent when in the expanded condition.
7. A balloon expandable stent including at least one self-expandable part with a balloon expandable part.
8. The stent of claim 7 wherein the two parts are in juxtaposition.
9. The stent of claim 7 wherein the self-expanding part is at the proximal end of the stent.
10. The stent of claim 9 wherein the self-expanding part is flared.
11. The stent of claim 7 wherein the self-expandable part has a larger overall diameter than the rest of the stent.
12. The stent of claim 1 including a self-expanding part at each end of the other part.
13. A bifurcated stent comprised of three components including a trunk and two branches and in which at least one part is capable of self-expansion and at least one part is radially expandable by means of an interior radial force.
14. The bifurcated stent of claim 13 in which the trunk component and one branch component are self-expandable and the other branch component is balloon expandable.
15. The bifurcated stent of claim 13 in which the trunk component is self expandable and the branch components are balloon expandable.

Fig. 1

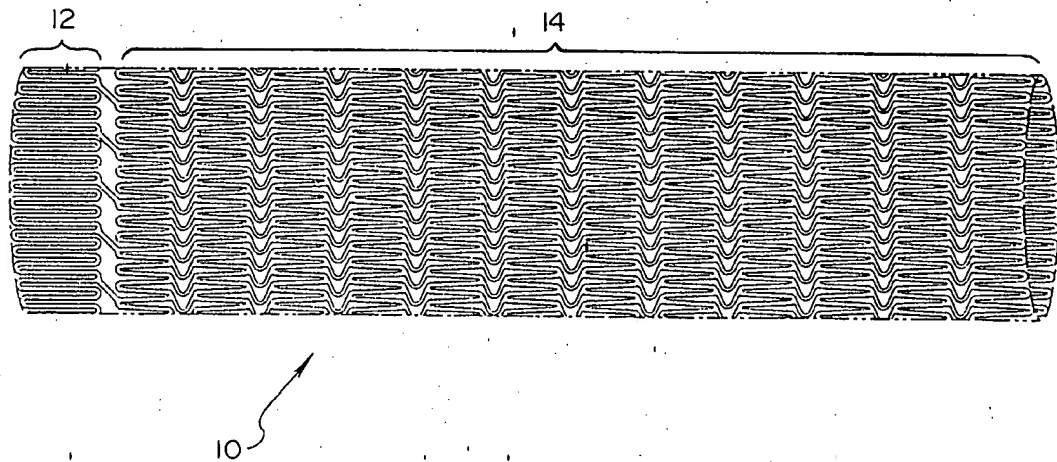


Fig. 2

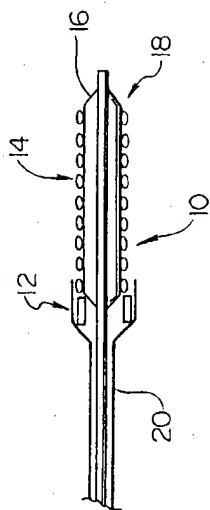


Fig. 3

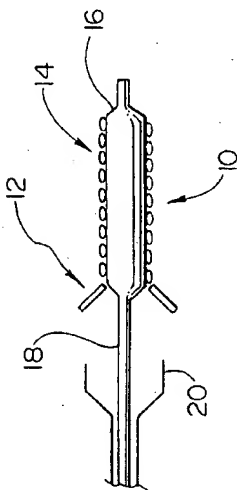


Fig. 4

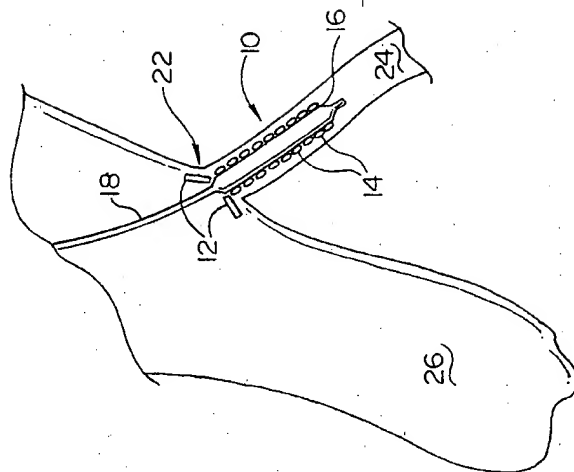


Fig. 5

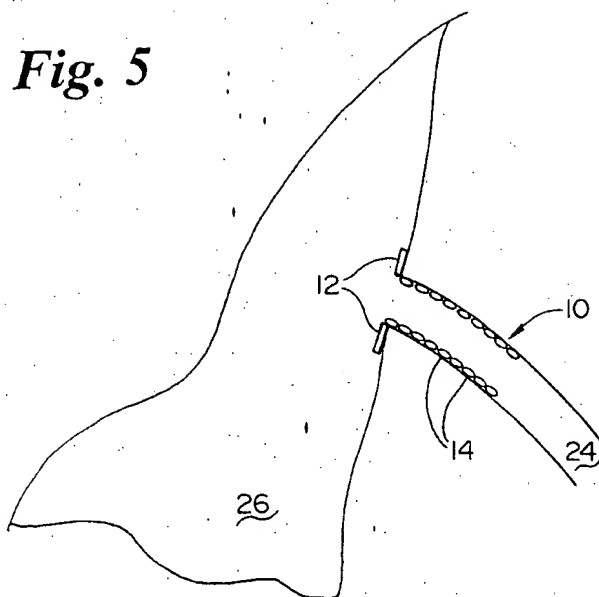


Fig. 6

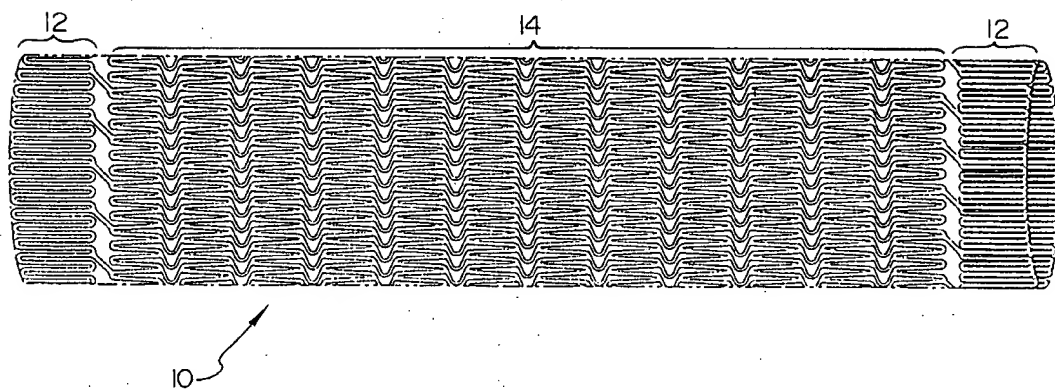
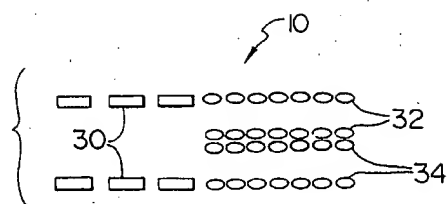
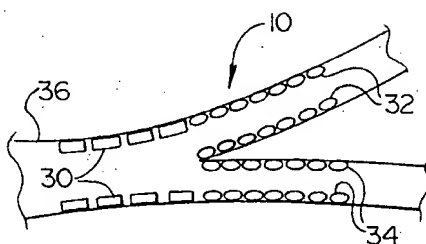
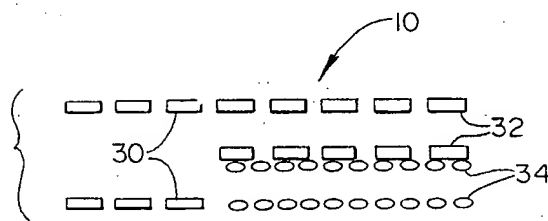
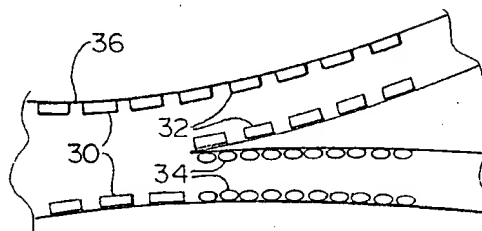


Fig. 7**Fig. 8****Fig. 9****Fig. 10**

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/11602

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5366504 A (ERIK ANDERSEN ET AL), 22 November 1994 (22.11.94), column 9, line 52 - column 10, line 26, figures 7a-7d	1-12
Y	--	13-15
Y	US 5741325 A (ELLIOT L. CHAIKOF ET AL), 21 April 1998 (21.04.98), figure 6	13-15
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Information on patent family members

28/09/99

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5366504 A	22/11/94	CA 2139564 A	20/01/94
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		JP 7509152 T	12/10/95
		US 5674276 A	07/10/97
		US 5876445 A	02/03/99
		WO 9401056 A	20/01/94
		US 5405378 A	11/04/95
		US 5653748 A	05/08/97
<hr/>			
US 5741325 A	21/04/98	AU 8012394 A	01/05/95
		WO 9509586 A	13/04/95
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